

U.S.S.N. 09/766,362

Filed: January 19, 2001

AMENDMENT AND RESPONSE TO OFFICE ACTION**In the Claims**

1. (currently amended) A composition for the nasal administration of a drug in a dry powder form suitable for administration to the nasal region,

the dry powder form comprising microparticles having an average particle size of between 10 and 20 microns and ~~consisting essentially of~~ comprising the drug and an excipient selected from the group consisting of diketopiperazines and synthetic polymers selected from the group consisting of poly(hydroxy acids) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, polyvinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids, polyurethanes and co-polymers thereof, celluloses, poly(butyric acid), poly(valeric acid), poly(lactide-co-caprolactone), copolymers and mixtures thereof.

2. (original) The composition of claim 1 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

3. (original) The composition of claim 2 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

4. (currently amended) The composition of claim 1 wherein the ~~drug is formulated in a polymeric carrier~~ diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.

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5. (currently amended) The composition of claim 1 wherein the ~~drug is formulated in a diketopiperazine formulation~~ diketopiperazine is formed by cyclodimerization of amino acid ester derivatives.

6. (canceled) The composition of claim 1 wherein the dry powder formulation consists essentially of drug.

7. (currently amended) A drug delivery device for nasal administration comprising a drug in a dry powder form in a dosage formulation for administration to the nasal region, and

a device for delivering a measured dose of the drug to the nasal mucosa,

wherein the dry powder form comprises microparticles having an average particle size of between 10 and 20 microns and ~~consisting essentially of comprising~~ the drug and an excipient selected from the group consisting of diketopiperazines and synthetic polymers selected from the group consisting of poly(hydroxy acids) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylenes, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, polyvinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexyl methacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and co-

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~~polymers thereof, celluloses, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), copolymers and mixtures thereof.~~

8. (original) The device of claim 7 wherein the device is a nasal insufflator.

9. (original) The device of claim 7 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

10. (original) The device of claim 7 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

11. (currently amended) The device of claim 7 wherein the ~~drug is formulated in a polymeric carrier~~ diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.

12. (currently amended) The device of claim 7 wherein the ~~drug is formulated in a diketopiperazine formulation~~ diketopiperazine is formed by cyclodimerization of amino acid ester derivatives.

13. (canceled) The device of claim 7 wherein the dry powder formulation consists essentially of drug.

14. (currently amended) A method of administering a drug to the nasal region of a patient in need thereof, comprising nasally administering a dry powder suitable for nasal administration,

wherein the dry powder form comprises microparticles having an average particle size of between 10 and 20 microns and ~~consisting essentially of~~ comprising the drug and an excipient

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~~selected from the group consisting of diketopiperazines and synthetic polymers selected from the group consisting of poly(hydroxy acids) and copolymers thereof, polyanhydrides, polyesters, polyorthoesters, polyamides, polycarbonates, polyalkylones, poly(ethylene glycol), poly(ethylene oxide), poly(ethylene terephthalate), polyvinyl alcohols, polyvinyl ethers, polyvinyl esters, polyvinyl halides, polyvinylpyrrolidone, polyvinyl chloride, polystyrene, polysiloxanes, polymers of acrylic and methacrylic acids, poly(methyl methacrylate), poly(ethyl methacrylate), poly(butyl methacrylate), poly(isobutyl methacrylate), poly(hexyl methacrylate), poly(isodecyl methacrylate), poly(lauryl methacrylate), poly(phenyl methacrylate), poly(methyl acrylate), poly(isopropyl acrylate), poly(isobutyl acrylate), poly(octadecyl acrylate), polyurethanes and copolymers thereof, celluloses, poly(butic acid), poly(valeric acid), poly(lactide-co-caprolactone), copolymers and mixtures thereof.~~

15. (original) The method of claim 14 wherein the drug is selected from the group consisting of antihistamine, vasoconstrictors, antiinflammatories and analgesics.

16. (original) The method of claim 14 wherein the antihistamine is selected from the group consisting of chlorpheniramine and azelastine.

17. (currently amended) The method of claim 14 wherein the ~~drug is formulated in a polymeric carrier~~ diketopiperazine is a substitution derivative selected from the group consisting of diketomorpholines, diketooxetanes and diketodioxanes.

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18. (currently amended) The method of claim 14 wherein the ~~drug is formulated in a~~
diketopiperazine ~~formulation~~ diketopiperazine is formed by cyclodimerization of amino acid
ester derivatives.

19. (canceled) The method of claim 14 wherein the dry powder formulation consists
essentially of drug.

20. (new) The composition of claim 1 formed by spray drying.

21. (new) The device of claim 7 wherein the microparticles are formed by spray drying